4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-3203]

Wyeth Pharmaceuticals Inc. et al.; Withdrawal of Approval of 121 New Drug Applications and 161 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of June 21, 2017 (82 FR 28322). The document announced the withdrawal of approval of 121 new drug applications (NDAs) and 161 abbreviated new drug applications from multiple applicants, withdrawn as of July 21, 2017. The document indicated that FDA was withdrawing approval of NDA 204508, Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%, after receiving a request from the NDA holder, Baxter Healthcare Corp. (Baxter), 32650 N. Wilson Rd., Round Lake, IL 60073. Before the approval of NDA 204508 was withdrawn, Baxter informed FDA that it did not want the approval of this NDA withdrawn. Because Baxter timely requested that approval of this NDA not be withdrawn, the approval of NDA 204508 is still in effect.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Wednesday, June 21, 2017, appearing on page 28322 in FR Doc. 2017-12908, the following correction is made:

On page 28329, in table 1, the entry for NDA 204508 is removed.

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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